CHAPTER 6
GENERAL PHARMACY LICENSES
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 2]

657—6.1(155A) Applicability. A general pharmacy is a location where a pharmacist practices in accordance with pharmacy laws. This chapter does not apply to hospital pharmacy licenses issued pursuant to 657—Chapter 7.

657—6.2(155A) Personnel.

6.2(1) *Pharmacist in charge.* Each pharmacy shall have one pharmacist in charge who is responsible for, at a minimum, the following:

a. Ensuring that a pharmacist performs prospective drug review as specified in rule 657—8.19(155A);

b. Ensuring that a pharmacist provides patient counseling as specified in rule 657—8.20(155A);

c. Dispensing drugs to patients, including any packaging, preparation, compounding, and labeling of the drug which is performed by pharmacy personnel;

d. Delivering drugs to the patient or the patient's agent;

e. Ensuring that patient medication records are maintained as specified in rule 657—8.18(155A);

f. Training pharmacy technicians and supportive personnel;

g. Establishing policies for procurement of prescription drugs and devices and other products dispensed from the pharmacy;

h. Disposing of and distributing drugs from the pharmacy;

i. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations;

j. Establishing and maintaining effective controls against the theft or diversion of prescription drugs and records for such drugs;

k. Legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, or regulations governing the practice of pharmacy.

6.2(2) *Pharmacists.* The pharmacist in charge shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the pharmacy competently, safely, legally, and adequately to meet the needs of the patients of the pharmacy.

a. Pharmacists shall assist the pharmacist in charge in meeting the responsibilities identified in subrule 6.2(1).

b. Pharmacists are solely responsible for the direct supervision of pharmacy technicians and for designating and delegating duties pursuant to 657—Chapter 22 and rule 657—8.1(155A).

c. All pharmacists shall be responsible for complying with state and federal laws or rules governing the practice of pharmacy.

6.2(3) *Other personnel.*

a. Pharmacist-interns, pursuant to the requirements and limitations contained in 657—Chapter 4, shall assist the pharmacist in charge in meeting the responsibilities identified in subrule 6.2(1).

b. Pharmacy technicians and other support personnel, pursuant to the requirements and limitations contained in 657—Chapter 22, shall assist the pharmacist in charge in meeting the responsibilities identified in subrule 6.2(1).

657—6.3(155A) Reference library. References may be printed or computer-accessed. A reference library shall be maintained which includes, as a minimum, one reference from each of the following:

1. Current Iowa pharmacy laws, rules, and regulations.
2. A patient information reference, updated at least annually, such as:

- United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient);
- Facts and Comparisons Patient Drug Facts; or
- Leaflets which provide patient information in compliance with rule 657—8.20(155A).

3. A current reference on drug interactions, such as:

- Phillip D. Hansten's Drug Interactions; or
- Facts and Comparisons Drug Interactions.

4. A general information reference, updated at least annually, such as:

- Facts and Comparisons with current supplements;
- United States Pharmacopeia Dispensing Information, Volume I (Drug Information for the Healthcare Provider); or
- American Hospital Formulary Service with current supplements.

5. A current drug equivalency reference, including supplements, such as:

- Approved Drugs Products With Therapeutic Equivalence Evaluations (FDA Orange Book);
- ABC - Approved Bioequivalency Codes; or
- USP DI, Volume III.

6. Basic antidote information or the telephone number of a poison control center.
7. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served.

657—6.4(155A) Prescription department equipment. The prescription department shall have, as a minimum, the following:

1. Measuring devices such as syringes or graduates capable of measuring 1 ml. to 250 ml.;
2. Suitable refrigeration unit. The temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration;
3. Other equipment as necessary for the particular practice of pharmacy.

657—6.5(155A) Environment.

6.5(1) *Space, equipment, and supplies.* There shall be adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy.

6.5(2) *Clean and orderly.* The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be in good operating condition and maintained in a sanitary manner.

6.5(3) *Sink.* A pharmacy shall have a sink with hot and cold running water within the prescription department, available to all pharmacy personnel, and maintained in a sanitary condition.

6.5(4) *Counseling area.* A pharmacy shall contain an area which is suitable for confidential patient counseling. Such area shall:

a. Be easily accessible to both patients and pharmacists and not allow patient access to prescription drugs;

b. Be designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

6.5(5) *Lighting and ventilation.* The pharmacy shall be properly lighted and ventilated.

6.5(6) *Temperature.* The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs.

657—6.6(155A) Security. Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of prescription drugs, and records for such drugs.

6.6(1) The prescription department shall be locked by key or combination so as to prevent access when a pharmacist is not on site except as provided in subrule 6.6(2).

6.6(2) In the temporary absence of the pharmacist, only the pharmacist in charge may designate persons who may be present in the prescription department to perform functions designated by the pharmacist in charge. Activities identified in subrule 6.6(3) may not be performed during such temporary absence of the pharmacist. A temporary absence is an absence of short duration not to exceed two hours, during which time the prescription department is closed.

6.6(3) Activities which shall not be designated and shall not be performed during the temporary absence of the pharmacist include:

a. Dispensing or distributing any prescription medications to patients or others.

b. Providing the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.

c. Conducting prospective drug use review or evaluating a patient's medication record for purposes identified in rule 657—8.19(155A).

d. Providing patient counseling, consultation, or patient-specific drug information.

e. Making decisions that require a pharmacist's professional judgment such as interpreting or applying information.

f. Prescription transfers to or from other pharmacies.

657—6.7(155A) Procurement and storage of drugs. The pharmacist in charge shall have the responsibility for the procurement and storage of drugs.

6.7(1) Prescription drugs and devices and nonprescription Schedule V controlled substances shall be stored within the prescription department or a secure storage area.

6.7(2) All drugs shall be stored at the proper temperature, as defined by the following terms:

a. Controlled room temperature — temperature maintained thermostatically between 15 degrees and 30 degrees Celsius (59 degrees and 86 degrees Fahrenheit);

b. Cool — temperature between 8 degrees and 15 degrees Celsius (46 degrees and 59 degrees Fahrenheit) which may, alternatively, be stored in a refrigerator unless otherwise specified on the labeling;

c. Refrigerate — temperature maintained thermostatically between 2 degrees and 8 degrees Celsius (36 degrees and 46 degrees Fahrenheit); and

d. Freeze — temperature maintained thermostatically between -20 degrees and -10 degrees Celsius (-4 degrees and 14 degrees Fahrenheit).

6.7(3) Out-of-date drugs or devices.

a. Any drug or device bearing an expiration date shall not be dispensed beyond the expiration date of the drug or device.

b. Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are disposed of properly.

657—6.8(155A) Records. Every inventory or other record required to be kept under Iowa Code chapters 124 and 155A or 657—Chapter 6 shall be kept at the licensed location of the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the inventory or record except as otherwise required in this rule. Controlled substance records shall be maintained in a readily retrievable manner in accordance with federal requirements. Those requirements, in summary, are as follows:

6.8(1) Controlled substance records shall be maintained in a manner to establish receipt and distribution of all controlled substances;

6.8(2) Records of controlled substances in Schedule II shall be maintained separately from records of controlled substances in Schedules III, IV, and V and all other records;

6.8(3) A Schedule V nonprescription registry book shall be maintained in accordance with 657—subrule 10.13(13).

6.8(4) Invoices involving the distribution of Schedule III, IV, or V controlled substances to another pharmacy or practitioner must show the actual date of distribution; the name, strength, and quantity of controlled substances distributed; the name, address, and DEA registration number of the distributing pharmacy and of the practitioner or pharmacy receiving the controlled substances;

6.8(5) Copy 1 of DEA Order Form 222, furnished by the pharmacy or practitioner to whom Schedule II controlled substances are distributed, shall be maintained by the distributing pharmacy and shall show the quantity of controlled substances distributed and the actual date of distribution;

6.8(6) Copy 3 of DEA Order Form 222 shall be properly dated, initialed, and filed and shall include all copies of each unaccepted or defective order form and any attached statements or other documents;

6.8(7) If controlled substances, prescription drugs, or nonprescription drug items are listed on the same record, the controlled substances shall be asterisked, red-lined, or in some other manner readily identifiable from all other items appearing on the records;

6.8(8) Suppliers' invoices of prescription drugs and controlled substances shall clearly record the actual date of receipt by the pharmacist or other responsible individual;

6.8(9) Suppliers' credit memos for controlled substances and prescription drugs shall be maintained;

6.8(10) A biennial inventory of controlled substances shall be maintained for a minimum of four years from the date of the inventory;

6.8(11) Reports of theft or significant loss of controlled substances shall be maintained;

6.8(12) Reports of surrender or destruction of controlled substances shall be maintained;

6.8(13) Records, except when specifically required to be maintained in original or hard-copy form, may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

a. The records maintained in the alternative system contain all of the information required on the manual record; and

b. The data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

657—6.9(126) Return of drugs and appliances. For the protection of the public health and safety, prescription drugs shall not be returned, exchanged, or resold unless, in the professional judgment of the pharmacist, the integrity of the prescription drug has not in any way been compromised. Prescription drugs may, however, be returned and reused as authorized in 657—subrule 8.9(6). No items of personal contact nature which have been removed from the original package or container after sale shall be accepted for return, exchanged, or resold by any pharmacist.

657—6.10(155A) Training and utilization of pharmacy technicians. General pharmacies utilizing pharmacy technicians shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians. Pharmacy policies shall specify the frequency of review. Technician training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of technician training shall be available for inspection by the board or an agent of the board.

These rules are intended to implement Iowa Code sections 124.303, 124.306 to 124.308, 126.10, 155A.13, 155A.31, 155A.32, and 155A.35.

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